UNITED STATES DISTRICT COURT EASTERN DISTRICT OF TENNESSEE AT GREENEVILLE

UNITED STATES OF AMERICA)	
)	
V.)	NO. 2:13-CR-56
)	
ANINDYA KUMAR SEN, <i>ET AL</i>)	

REPORT AND RECOMMENDATION

The defendants, Dr. Anindya Kumar Sen, Patricia Posey Sen, and East Tennessee Cancer and Blood Center ["East Tennessee Cancer"] have filed a joint motion [Doc. 61] to dismiss the Second Superseding Indictment for vindictive prosecution, prosecutorial misconduct, and selective prosecution, or in the alternative, to compel discovery of prosecutorial abuses.¹ An evidentiary hearing was held on November 13 and 18, 2013.

The genesis of the charges in this case is in an investigation which began in February, 2012, by the Food and Drug Administration ["FDA"] of the McLeod Cancer and Blood Center ["McLeod"] in Johnson City, Tennessee. The FDA had been advised that McLeod had obtained and administered to cancer patients unapproved chemotherapy drugs manufactured outside of the United States. The primary investigator assigned to that case was Special Agent Robert West of the FDA, who also is the lead investigator in the present

¹It may be technically correct, as the United States points out in its response, that the original Indictment and the First Superseding Indictment remain viable. Nevertheless, it is clear that defendants want the *entire* case dismissed.

case.

Agent West, as part of his investigation of the McLeod case, contacted the Johnson City office of defendant East Tennessee Cancer to see if anyone in that medical practice had purchased and administered such unlawful drugs.² On March 27, 2012, he spoke with defendant Patricia Posey Sen, office manager of East Tennessee Cancer and spouse of codefendant Dr. Anindya Sen, by telephone, and was advised that East Tennessee Cancer did not purchase or use "foreign drugs."

On April 3, 2012, Agent West visited the offices of Meiko America, which had shipped unapproved foreign drugs to McLeod. While perusing Meiko's records, he noticed that allegedly unapproved foreign drugs also had been shipped to Dr. Sen at his clinic in Greeneville, Tennessee.

On April 5, 2012, Agent West, accompanied by FBI Special Agent Letitia Jones, went to the clinic. They first interviewed assistant office manager Larry Edgell. They then interviewed Edgell together with Ms. Sen, and finally Ms. Sen alone. Unbeknownst to the agents, their conversations were recorded, both visually and audibly, by surveillance cameras. As described in the report and recommendation regarding the defendants' joint motion to suppress, the agents gained access to misbranded or unapproved drugs which are the subject of the charges brought in this case. From Sen's attorney, Agent West was given additional drugs on April 12, 2012, which were located at Sen's Johnson City office.

² The Johnson City office is a "satellite office," with the "main" office of the defendants located at 1406 Tusculum Blvd., Suite 2000, in Greeneville, Tennessee.

On April 19, 2012, Agent West served a subpoena on East Tennessee Cancer seeking production of records relating to the subject drug purchases. Having learned of the surveillance recording, he also subpoenaed the digital video recorder from the Greeneville office, which he received on May 15, 2012.

Defendants allege that Agent West, Agent Jones, and AUSA M. Neil Smith, the assigned prosecutor in this case, engaged in various actions which exhibited a vindictive attitude toward the defendants.

Various meetings were held between Smith, the agents and counsel for the defendants. On November 13, 2012, at the first meeting, the results of the investigation to that point were summarized, which showed violations of the Food, Drug and Cosmetic Act ["FDCA"]. The next meeting on February 11, 2013 was unproductive. On February 12, 2013, Smith sent a letter to defense counsel that the United States would agree for Dr. Sen and Ms. Sen to plead guilty to misdemeanor violations with East Tennessee Cancer pleading guilty to health care fraud.

Defense counsel later met with AUSA Smith, Mr. Smith's supervisor Nancy Harr, and United States Attorney William Killian on April 3, 2013. On April 12, 2013, Mr. Killian sent a letter to defendants' attorneys in which he stated that he had reviewed the evidence in the case, and in his opinion the offer of misdemeanor pleas was "fair, reasonable, supported by overwhelming evidence, and is in accordance with the Principles of Federal Prosecution." The offer was declined by the defendants.

On June 11, 2013, the federal Grand Jury in Greeneville returned the first Indictment

in this case, charging the defendants with conspiracy to introduce misbranded drugs, introducing misbranded drugs, importing drugs contrary to law, and conspiracy to commit health care fraud.

On July 2, 2013, a subpoena was served on Attorney Warlick, counsel for East Tennessee Cancer, seeking records for patients who had received the drug Bevacizumab between March 2011 and February 2012. Meanwhile, records were reviewed from Oncology Supply, the U.S. drug distributor for the defendants' practice, which revealed that no Avastin, which is the approved U.S. version of Bevacizumab, had been sold to East Tennessee Cancer during that time period. The invoices provided from East Tennessee Cancer during that period showed that the only Bevacizumab sold to ETCBC in that time period was the unapproved drug Altuzan, which was produced in Turkey.

On July 9, 2013, a Superseding Indictment was returned, adding charges that Ms. Sen had made false statements to Agent West during their conversations on March 27 and April 5, 2012, about obtaining or using foreign drugs.

In early August 2013, records were obtained from the U.S. Postal Service in Greeneville showing that East Tennessee Cancer's assistant office manager Larry Edgell had mailed a package to Clinical Care in the United Kingdom on March 8, 2012.

Defendants presented proof from Elizabeth Charles, a registered nurse who is the oncology nurse at the Johnson City office. Nurse Charles recounted her encounter with Agent West on March 27, 2012, during which he told her about the investigation of McLeod. According to Ms. Charles, West asked her if anyone ever tried to get her to buy any

unapproved foreign drugs. She said no. He then asked her to have Ms. Sen call him, and she agreed. Nurse Charles testified also that Agent West and Agent Jones came to talk to her again in mid-April 2012. She testified that Agent West told her that Ms. Sen was the "biggest liar he ever saw," or words to that effect, which Charles perceived to be a clear attempt to discredit Ms. Sen.

Nurse Charles also testified that a co-worker, Eric Chlebisch, at some more recent time, had spoken to her about the case in detail. She said that Chlebisch told her about several meetings he had with Agent West. He told her that the defendants had rejected a plea deal for misdemeanor charges, and that their failure to accept the deal was the reason he and other employees were still being bothered by federal agents. She said that Chlebisch told her that Agent West was looking forward to "putting handcuffs on Dr. and Ms. Sen" and taking them to jail. He told her about the Sens' large net worth, that the clinic would not be open much longer, that West had been to Larry Edgell's house to pick up the surveillance tapes, and that Edgell's house was "a trash heap of filth, old cars, and overall dirty conditions." Chlebish told her that even though Dr. Sen did not know about the unlawful drugs, he should get the full 20 years because he "should have known."

Defendants also presented the testimony of Larry Edgell. After recounting the events at the April 5, 2012 encounter at East Tennessee Cancer with Agents West and Jones, he recounted a visit from them at his home a few weeks later regarding the surveillance system in the medical office. West told him that the recording was illegal, and that he did not like being recorded. He asked him if he had been listening to the interview with Ms. Sen on the

recording, to which Mr. Edgell responded that he had not. Agent Jones asked why Edgell was not curious about what Ms. Sen had said.

On August 9, 2013, Mr. Edgell stated that Agent Jones and AUSA Smith, traveling in a white car, had pulled in behind him when he parked in the Laughlin Hospital parking lot in Greeneville. Agent Jones asked Edgell if he wanted to go somewhere else and talk, but he preferred to talk there. AUSA Smith allegedly opened a folder and told him it contained a customs declaration for foreign drugs shipped from Greeneville back to the United Kingdom by Edgell. He testified that Smith told him that it was a crime to smuggle unlawful drugs out of the country, and that Edgell could either talk to the government or face being indicted for drug smuggling. Edgell maintained he had done nothing wrong. He said that Jones and Smith continued to disparage the defendants, and that they also accused him of lying.

Edgell told his wife about the encounter in the parking lot. She said that she had seen the white care with Jones and Smith parked in her driveway while Edgell was away with their children at a birthday party. They had knocked on the door and she did not answer. After twenty minutes, they left.

On October 8, 2013, a Second Superceding Indictment was returned by the Grand Jury. In this Indictment, all felony counts against Dr. Sen were dropped, as well as all allegations that he was involved in health care fraud. This Indictment added twenty-nine misdemeanor violations of the FDA for mislabeling. However, forty-four felony counts of health care fraud were added against Mrs. Sen.

As stated in the title of this motion, the bases for dismissal of the Indictments alleged by the defendants in this motion is prosecutorial vindictiveness and misconduct, and selective prosecution.

From the inception of our governmental structure, prosecution of criminal offenses, including whom to charge and what to charge them with, has been an exclusive function of the executive branch. Prosecuting attorneys in the federal system are extensions of the President, carrying out his responsibility to enforce and administer, in a just and fair manner, the laws of the land. In doing this, prosecutors have been afforded extremely wide discretion regarding what individuals to charge with offenses, and what offenses to allege against them. *United States v. Armstrong*, 517 U.S. 456, 464 (1996).

The judicial branch is not endowed with the authority, or the responsibility, to second-guess these decisions, except in cases in which there has been a flagrant and obvious abuse of that discretion, or where considerable evidence exists of retaliatory motives. Courts are not only encouraged to refrain from micro-managing prosecutorial decisions; they are *forbidden* to even question them except in very narrow circumstances. *See, Wayte v. United States*, 470 U.S. 598, 607 (1985)

The limits on prosecutorial discretion which are obvious are those in cases initiated by a discriminatory animus prohibited by the Constitution, such as purposely charging persons with offenses, or more serious offenses, because of their race, religious affiliation, or other characteristics of the defendant that implicates equal protection. Beyond these "bright line" circumstances, courts may interfere with prosecutorial decisions and dismiss

charges only where there is strong proof that those decisions were made to stifle the exercise of a clear constitutional right, or to unfairly punish a defendant for the exercise of such a right.

Defendants' vindictive prosecution argument is based primarily upon the severity of the charges leveled at the defendants in the original Indictment, which they assert was in retribution for their refusal to accept the government's offer during plea negotiations. Mrs. Sen also asserts that the extensive felony charges against her for health care fraud in the Second Superseding Indictment were in retaliation for her opposition to a motion by the government to prohibit defendants' use of the video and audio recordings of the interviews conducted by Agent West on April 5, 2012 in the defendants' break room.³

In order to be entitled to relief, a defendant who asserts vindictive prosecution must show "(1) exercise of a protected right; (2) a prosecutorial stake in the exercise of that right; (3) unreasonableness of the prosecutor's conduct; [and] (4) the intent to punish the defendant for exercise of the protected right." *United States v. Suarez*, 263 F.3d 468, 479 (6th Cir. 2001). If the defendant meets its burden on these elements and establishes a "reasonable likelihood of vindictiveness," the burden shifts to the government to rebut "the presumption with 'objective on-the-record explanations' such as 'governmental discovery of previously unknown evidence...." *United States v. LaDeau*, ___ F.3d ___, 2013 WL 5878214 (6th Cir. 2013), at p. 7, citing *Bragan v. Poindexter*, 249 F.3d 476, 482 (6th Cir. 2001).

³As discussed in an earlier Order; see, Document 59.

The leading case where a claim of prosecutorial vindictiveness is based upon a defendant's rejection of a plea offer is *Bordenkircher v. Hayes*, 434 U.S. 357 (1978). In that case, a defendant's refusal to accept a plea to a felony conviction resulted in his indictment as a habitual criminal. After being convicted, he was given a life sentence. The Court noted that the defendant was properly chargeable under the recidivist statute, and that he made a conscious decision to reject the plea bargain which ultimately led to his conviction as a habitual criminal and the resultant life sentence. The defendant argued he was being "punished" for the exercise of his constitutional right to a jury trial. However, the Court stated that "in the give-and-take of plea bargaining, there is no such element of punishment or retaliation so long as the accused is free to accept or reject the prosecution's offer." *Id*, at 363. Also, Justice Stewart stated that the "Court has necessarily accepted as constitutionally legitimate the simple reality that the prosecutor's interest at the bargaining table is to persuade the defendant to forgo his right to plead not guilty." *Id*. at 364.

Bordenkircher does point out that the defendant made his choice with knowledge that he faced life in prison if he declined to simply plead guilty to the felony. However, this Court does not believe that a defendant must know the *complete* extent of the more serious charges the prosecutor may elect to bring for *Bordenkircher* to apply. Here, all defendants were represented by extremely competent counsel, who knew that the potential existed for much more serious charges based upon the sheer numbers of unapproved drugs found in the defendants' possession and control.

Defendants also assert that they were not individually free to accept the plea offer if

a co-defendant chose not to do so. However, it is appropriate for a plea to be conditioned upon all defendants' acceptance. *United States v. Martin*, 516 Fed. Appx. 433, 442-43 (6th Cir. 2013).

For these reasons, the Court finds that the charges brought in the original Indictment were not the result of retaliation for exercise of a protected right, but rather was the permissible exercise of leverage under *Bordenkircher*.

Defendants also assert that the charges brought were not supported by probable cause, and that instead the government was on an outright punitive expedition against them. However, probable cause was established by the action of the grand jury in bringing the Indictment. As stated in *Suarez, supra*, at 281, "[t]he defendant's main protection against the bringing of unfounded criminal charges, however, is through the institution of the grand jury." After the original Indictment, except for the charges against Mrs. Sen for health care fraud, the charges against Dr. Sen and the practice *lessened* in severity.

Ms. Sen argues that the addition of the felony counts against her in the Second Superceding Indictment manifests vindictiveness for the defendants' demand for *Brady/Giglio* material on October 1, 2013. However, the exact charges to be brought in the Second Superceding Indictment were approved on September 26, 2013, five days before the demand for *Brady* material. *See*, Doc. 71-2.

Mrs. Sen and the corporate defendant also argue that the felony charges in the Second Superseding Indictment were retaliatory, otherwise they would have been brought in the earlier Indictments. However, the government offers compelling evidence that the charges

of insurance fraud were believed unprovable until the information relating to patient records, including those who had claims submitted to insurance companies, was obtained pursuant to a subpoena issued July 2, 2013. When this information was received, further interviews with ETCBC employees revealed Mrs. Sen's role in reviewing these items before they were submitted for payment. The Court finds that this information was not available until after the First Superceding Indictment was obtained, and was certainly not available when the original Indictment was sought. Thus, this was not "loading up" because of rights asserted by the defendants, but rather was the result of continuing, and fair, investigation.

The Court is of the opinion that there was no vindictive or unfounded prosecution. While the Court concludes that a case of prosecutorial vindictiveness has not been made out under *Suarez* and related cases, the issues of misconduct and selective prosecution must also be addressed.

As an initial matter, post-indictment conduct cannot be considered in dismissing an indictment. *Bank of Nova Scotia v. United States*, 487 U.S. 250, 258 (1988). However, since there were subsequent indictments and since much of the alleged misconduct occurred before the superceding indictments were sought, these matters must be discussed.

The primary episode of alleged misconduct was the interview of Larry Edgell by Agent Jones and AUSA Smith, and their antecedent attempts to locate him at his residence, which greatly upset his wife.

AUSA Smith admittedly told Mr. Edgell that returning unapproved drugs to England was a violation of law. Edgell claims he took that as a threat to either testify as the

government wanted, or be indicted. Agent Jones testified that AUSA Smith merely told him, in a matter-of-fact fashion, of the potential peril involved in mailing the drugs back to the United Kingdom. Mr. Edgell's perception was wrong. AUSA Smith merely stated a legal conclusion after finding Mr. Edgell's signature on the Customs' document when the drugs were mailed. Agent Jones' testimony that the discussion was civil is believed. Naturally, the very presence of a prosecuting attorney in conversing with a hostile witness could be intimidating.⁴ However, these facts do not show a basis for dismissing the charges against the defendants.

The final issue is the alleged selective prosecution of these defendants versus the principals in the McLeod investigation.

A prosecutor selectively prosecutes someone when three things occur. First, he must single out a person belonging to an identifiable group, such as those of a particular race or religion, or a group exercising constitutional rights, for prosecution even though he has decided not to prosecute persons not belonging to that group in similar situations....Second, he must initiate the prosecution with a discriminatory purpose. Finally, the prosecution must have a discriminatory effect on the *group* which the defendant belongs to.

United States v. Anderson, 923 F.2d 450, 453 (6th Cir. 1991). Here, no showing has been made that Dr. Sen or his co-defendants belong to an identifiable group which has been singled out. Physicians do not constitute a "group" in the selective prosecution sense. Likewise, there can be no reasonable argument that the investigation of these defendants, based upon records accidentally discovered during the McLeod investigation, and the

⁴Mr. Edgell was never intimidated.

subsequent prosecution, were initiated on a discriminatory basis. This conclusion alone is enough to dispense with the selective prosecution claim.

Defendants argue that doctors and medical entities in the Mcleod prosecution were not treated as harshly as they are being treated, specifically, that Dr. Lamb and Dr. Famoyin were not charged with any crimes. But those doctors were not managing partners in the McLeod practice. The doctors who "called the shots" and who ordered the foreign drugs, Kincaid and Combs, actively concealed their activities from Lamb and Famoyin. Dr. Sen and his office manager, Mrs. Sen, were the decision makers at ETCBC. The situations are markedly different. Again, it must be emphasized that the present defendants can make no showing of prejudicial prosecution of any group to which they belong. This claim is without merit.

Finally, defendants request that if the Court does not find they have met their burden regarding vindictive prosecution, prosecutorial misconduct, and selective prosecution, they should be permitted to discover the Grand Jury transcripts to ferret out such evidence. The standard for obtaining such permission is "rigorous." *United States v. Wilson*, 262 F.3d 305, 315 (4th Cir. 2001). The probability of vindictiveness must be far more "self-evident" to justify their requested discovery. The Court cannot sanction such a fishing expedition with the facts presently in the record.

There is no compelling evidence of vindictive prosecution, misconduct, or selective prosecution to support the requested relief of dismissing this case. It is respectfully

recommended that the motion to	o dismiss (I	Doc. 61) ł	be denied.5
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Respectfully submitted:

s/ Dennis H. Inman
UNITED STATES MAGISTRATE JUDGE

⁵Any objections to this report and recommendation must be filed within fourteen (14) days of its service or further appeal will be waived. 28 U.S.C. 636(b)(1).